

REMARKS/ARGUMENTS

Claims 1 and 3-13 are pending, claims 5-8 and 13 having been withdrawn from consideration. By this Amendment, claim 2 is cancelled, and claims 1, 3 and 9 are amended. Support for the amendments to claims 1, 3 and 9 can be found, for example, in the present specification, paragraph [0018], and in original claims 1, 3 and 9. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Personal Interview

Applicants appreciate the courtesies extended to Applicants' representative by Examiner Duffy during the February 25, 2009 Personal Interview. Applicants' separate record of the substance of the interview is incorporated in the following remarks.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1-4 and 9-12 as indefinite under 35 U.S.C. §112, second paragraph. By this Amendment, claim 2 is cancelled, rendering the rejection moot as to that claim. As to the remaining claims, Applicants respectfully traverse the rejection.

The Office Action asserts that claims 1-4 and 9-12 are indefinite for failing to recite essential steps of an immunological assay. *See* Office Action, page 3. However, the Office Action provides no rationale for why such steps must be explicitly recited in the claims. As discussed during the Personal Interview, claims 1, 3 and 4 are directed a pretreatment for an immunoassay. There is no reason why pre-treatment claims should be required to recite "an immunological assay." One of ordinary skill in the art could readily determine whether or not a particular procedure is an immunological assay. No further detail is required in the claims – the metes and bounds of the claim are clear. The Office Action appears to object not to the

clarity of the claims, but rather to its breadth. As is well settled, breadth of a claim is not to be equated with indefiniteness. *See* MPEP §2173.04 (citing *In re Miller*, 169 U.S.P.Q. 597 (C.C.P.A. 1971)).

For the foregoing reasons, claims 1, 3, 4 and 9-12 are definite. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

#### Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1-4 and 9-12 under 35 U.S.C. §102(b) over Waki, H., et al., "Impaired Multimerization of Human Adiponectin Mutants Associated with Diabetes," J. Bio. Chem., 278 (41): 40352-63 (2003) ("Waki"). By this Amendment, claim 2 is cancelled, rendering the rejection moot as to that claim. As to the remaining claims, Applicants respectfully traverse the rejection.

Claim 1 recites "[a] method of pretreating a sample in preparation for immunologically assaying a total amount of adiponectin present in the sample, comprising: adding at least one reactant selected from the group consisting of an acid or a salt thereof, a surfactant, and a protease to the sample; and allowing the reactant to react with the sample without boiling the combined sample and reactant; wherein the sample is an adiponectin multimer-containing sample" (emphasis added). Claim 9 recites "[a] method for measuring a total amount of adiponectin present in a sample, comprising: adding at least one reactant selected from the group consisting of a reducing agent, an acid or a salt thereof, a surfactant, and a protease to the sample; allowing the reactant to react with the sample without boiling the combined sample and reactant; and subsequently performing an immunological assay of the sample for adiponectin; wherein the sample is an adiponectin multimer-containing sample" (emphasis added). Waki does not disclose or suggest such a method.

Claim 1 requires that an adiponectin-containing sample to treated with an acid or a salt thereof, a surfactant or a protease. Claim 1 has been amended to exclude reducing agents from the list of employed reactants. Waki discloses treating an adiponectin-containing sample with a reducing agent (dithiothreitol) and allowing the sample to react with the reducing agent without applying heat. See Waki, pages 40353 and 40355 (FIG. 2B – lane 3). However, there is no disclosure or suggestion in Waki of employing a reactant other than a reducing agent in converting adiponectin multimers. Accordingly, Waki fails to disclose or suggest each and every feature of claim 1.

Claim 9 requires that a treated adiponectin-containing sample be subjected to an immunological assay. As discussed above, Waki discloses treating an adiponectin-containing sample with a reducing agent and allowing the sample to react with the reducing agent without applying heat. However, there is no disclosure or suggestion in Waki that the particular sample, so-treated, is subsequently subjected to an immunoassay as in claim 9. While Waki discloses an academic study of adiponectin, there is no indication in Waki that particular techniques employed in such study would have any practical use as a pretreatment for an immunoassay. Accordingly, Waki fails to disclose or suggest each and every feature of claim 9.

As explained, claims 1 and 9 are not anticipated by Waki. Claims 3, 4 and 10-12 depend variously from claims 1 and 9 and, thus, also are not anticipated by Waki. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

#### Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1-4 and 9-12 under 35 U.S.C. §103(a) over Fruebis, J., et al., "Proteolytic cleavage product of 30-kDa adipocyte complement-related protein increases fatty acid oxidation in muscle and causes weight loss in mice," PNAS, 98 (4): 2005-

2010 (2001) ("Fruebis"). By this Amendment, claim 2 is cancelled, rendering the rejection moot as to that claim. As to the remaining claims, Applicants respectfully traverse the rejection.

Claims 1 and 9 are set forth above. Fruebis does not disclose or suggest such methods.

In each of claims 1 and 9, a sample containing adiponectin multimers is subjected to treatment with a reactant. As discussed in the present specification, treatment with such reactant has the effect of converting the various multimers in the sample to a certain specific form that provides substantially uniform reactivity for the purpose of conducting an immunoassay. *See* present specification, paragraph [0018]. In Fruebis, a monomer of adiponectin is fragmented using acetylated trypsin. *See* Fruebis, page 2007. There is no indication in Fruebis that multimers of adiponectin are treated with a reagent, such as a protease, as recited in claims 1 and 9. Fruebis, like Waki, discloses an academic study of adiponectin – there is no indication in Fruebis that particular techniques employed in such study would have any practical use as a pretreatment for an immunoassay.

Moreover, Applicants note that one of ordinary skill in the art would not expect that the techniques of Fruebis could or should be modified to obtain the methods of claims 1 and 9. As is evident from Pavjani et al., "Structure-Function Studies of the Adipocyte-secreted Hormone Acrp30/Adiponectin," The Journal of Biological Chemistry, Vol. 278, No. 11, Pages 9073-9085, 2003 ("Pavjani") (cited in July 13, 2006 Information Disclosure Statement), the protease employed in Fruebis (trypsin) is known to be ineffective in digestion of high- and medium-molecular weight multimers of adiponectin. *See* Pavjani, page 9081. Accordingly, in view of the teachings of Pavjani, one of ordinary skill in the art would not reasonably expect success upon employing the protease of Fruebis in an adiponectin multimer-containing sample, as required in claims 1 and 9.

Fruebis fails to disclose or suggest each and every feature of claims 1 and 9.

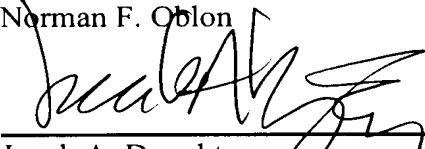
As explained, claims 1 and 9 would not have been rendered obvious by Fruebis. Claims 3, 4 and 10-12 depend variously from claims 1 and 9 and, thus, also would not have been rendered obvious by Fruebis. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1 and 3-13 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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